Decision Memo for Lung Volume Reduction Surgery (CAG-00115R2)

Decision Summary

CMS has determined that LVF	RS is reasonable and	necessary a	t additional	facilities that	t meet al	ternative s	standards
beyond those contained in ou		·					

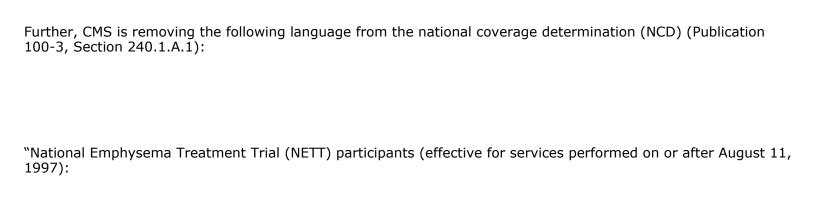
Therefore, CMS is revising paragraph A.2.c in CMS Publication 100-3 Section 240.1 as follows:

Effective for services performed on or after November 17, 2005, CMS determines that LVRS is reasonable and necessary when performed at facilities that are: (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or (2) approved as Medicare lung or heart-lung transplantation hospitals.

In addition, LVRS performed between January 1, 2004 and May 17, 2007, is reasonable and necessary when performed at facilities that: (1) were approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT); or (2) are approved as Medicare lung or heart-lung transplantation hospitals.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at www.cms.hhs.gov/coverage/lvrsfacility.pdf.

Lung or heart-lung transplant facilities must have Medicare-approved transplant status at the time the LVRS is performed. Facilities that seek to satisfy the facility requirement through Joint Commission certification must be certified at the time the LVRS is performed. NETT facilities that are not Medicare approved for lung or heart-lung transplantation need to become Joint Commission-certified or a Medicare-approved transplant facility within 18 months after the effective date of this decision, November 17, 2005, in order to continue to receive Medicare payment for LVRS after that date.



Medicare provides coverage to those beneficiaries who are participating in the NETT trial for all services integral to the study and for which the Medicare statute does not prohibit coverage."

The NETT clinical trial has ended and, therefore, the language is no longer applicable.

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Decision Memo

TO: Administrative File: CAG 00115R2

Lung Volume Reduction Surgery

FROM:

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Lead Medical Officer

SUBJECT: Coverage Decision Memorandum for Lung Volume Reduction Surgery

DATE: November 17, 2005

I. Decision

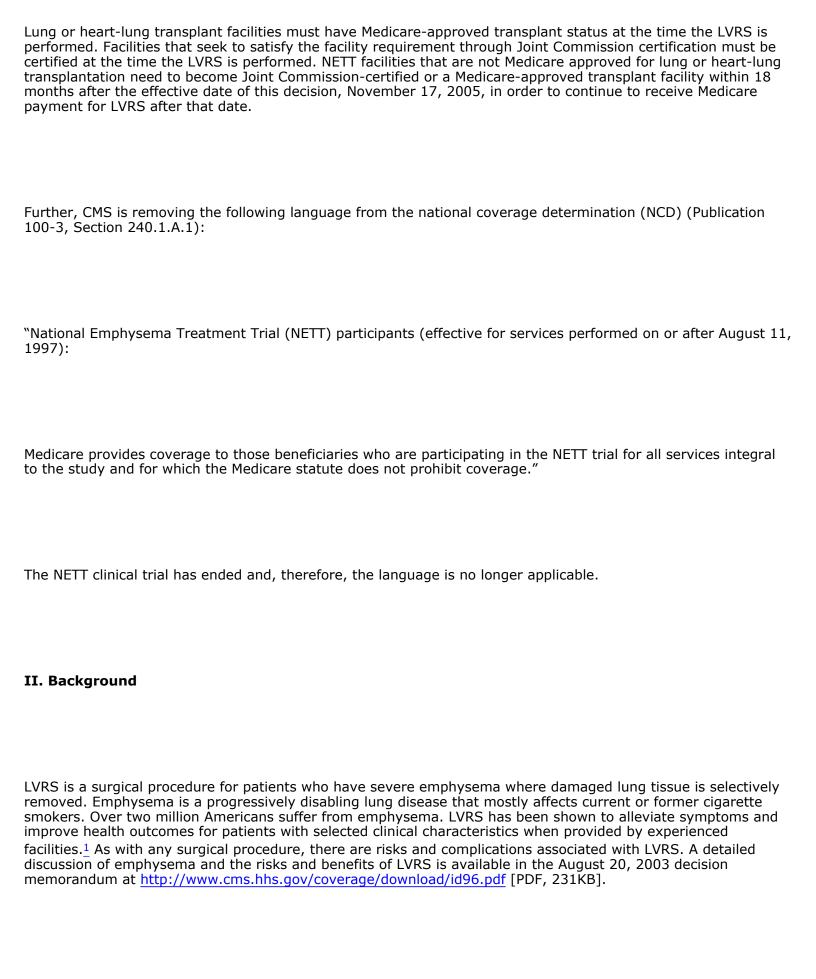
CMS has determined that LVRS is reasonable and necessary at additional facilities that meet alternative standards beyond those contained in our current NCD.

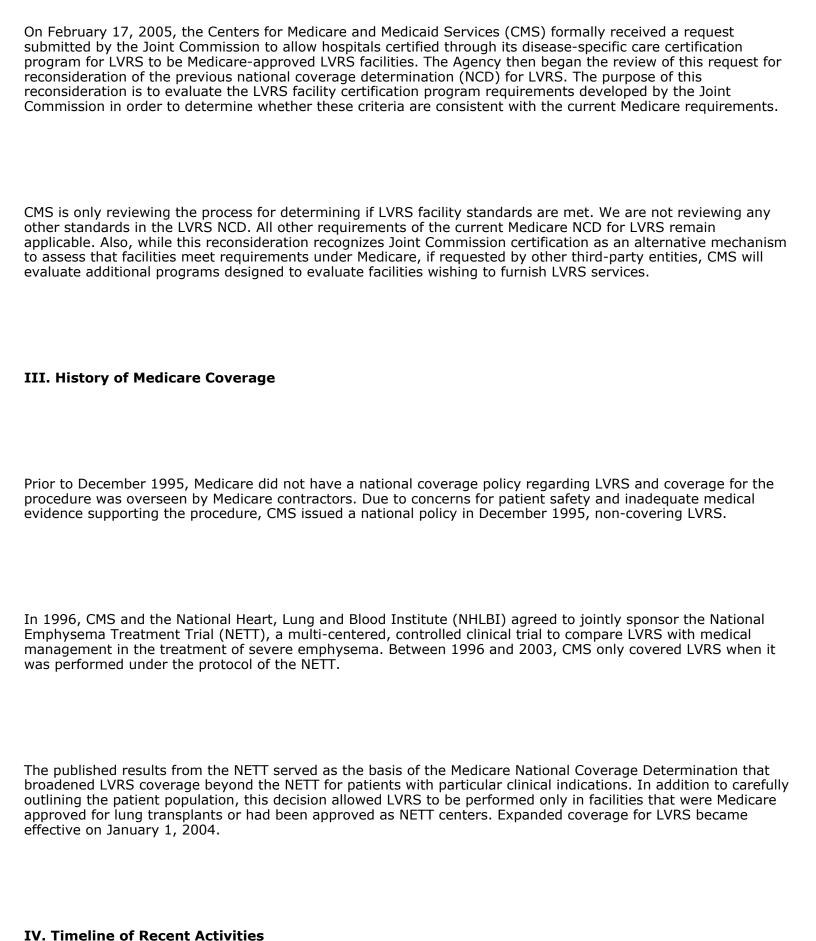
Therefore, CMS is revising paragraph A.2.c in CMS Publication 100-3 Section 240.1 as follows:

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August 20, 2003	CMS issues the Decision Memorandum announcing the intention of CMS to cover LVRS outside of clinical trials for specific clinical indications and the intention to consider allowing a third party program to certify Medicare-approved LVRS facilities.
January 1, 2004	The August 2003 decision becomes effective.
February 17, 2005	CMS opens a reconsideration for LVRS to review third party accreditation standards for facilities performing this procedure.
March 17, 2005	Initial 30-day public comment period closes.
August 18, 2005	Proposed Decision Memorandum is posted for public comment.
September 18, 2005	Public comment period for the proposed document closes.

V. FDA Status

LVRS is a surgical procedure that does not require FDA approval.

VI. Methods
In this memorandum, CMS compares the Joint Commission program requirements to the existing Medicare LVRS facility requirements that served as the basis for approving NETT centers and lung transplant centers in January 2004. Our examination consisted of:
 Reviewing the process used by the Joint Commission to develop their standards; and Comparing the Joint Commission standards with the general standards for LVRS facilities established by CMS to determine whether the Joint Commission's LVRS-specific certification criteria are at least equivalent to the CMS standards and therefore likely to identify facilities that will furnish LVRS in a reasonable and necessary manner.
Further, CMS explains why the designation of currently approved NETT facilities will terminate in the future due to the cessation of oversight provided by NHLBI. We provide an alternative method for those hospitals to become approved so that they may continue to receive Medicare payment for covered LVRS procedures.
VII. Assessment
1. Assessment questions
In this assessment, CMS seeks to address the following questions:
 Are the Joint Commission standards at least equivalent to the CMS standards used to select NETT and transplant centers in the January 2004 decision?

• Should facilities selected as NETT centers continue to be approved as LVRS facilities?
• What impact will the proposed transplant regulation have on LVRS approved facilities ² ?
2. Current CMS requirements for LVRS facilities
In the August 2003 decision memorandum, by selecting the sites that had been approved by NHLBI to participate in the NETT as Medicare-approved programs, CMS implicitly adopted the facility standards that had been utilized by NHLBI to identify facilities qualified to participate in the trial. These requirements included, among others, hat each facility had assembled an integrated team expert in pulmonary medicine, had a close working elationship with a lung or heart-lung transplantation center, and had the ability to provide relevant patient outcome data. CMS adopted the NHLBI-derived standards by restricting approved facilities initially to those that participated in the NETT in addition to Medicare-approved transplant centers which were presumed to have met the above criteria. The NHLBI standards are explicitly stated below:
The facility must ensure that all individuals who provide services and/or supervise services in the LVRS program are qualified to provide or supervise such services. The facility must identify a multidisciplinary LVRS team and describe the responsibilities of each member.

- The facility must identify a multidisciplinary LVRS team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of pulmonary medicine, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, and pulmonary radiological assessment.
- The primary surgeon participating in the program must have experience performing LVRS procedures.
- The pulmonary specialist(s) must have training and clinical expertise in managing and treating end-stage emphysema patients, have a firm understanding of pulmonary medicine and pulmonary rehabilitation, and have experience in managing patients undergoing LVRS.
- The facility must demonstrate a close working relationship with or be a Medicare lung or heart-lung transplantation center to ensure that patients are adequately evaluated for both LVRS and lung transplant prior to the surgical procedure.
- The facility must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, infectious disease control, pathology, radiology, physical therapy and blood banking as related to the provision of LVRS.
- The facility must establish and implement written policies to address and document adverse events that occur during the management of an LVRS patient.
- The facility must have a written informed consent process that informs each patient of: 1) the evaluation process; 2) the surgical procedure; 3) alternative treatments; 4) national and center-specific rates for potential surgical risks, hospital lengths of stays, 30-day mortality and other relevant outcome measures; 5) risk factors that could affect the success of the surgery; and 6) the patient's right to refuse the intervention.

In addition, NHLBI required that NETT facilities had the capacity to collect, analyze and provide pre-operative, post-operative and follow-up data. Accordingly, the facility's quality improvement program would utilize objective measures to evaluate the LVRS program's performance periodically with regard to LVRS services and outcomes. Services and outcomes could include, but were not limited to patient selection criteria, consent practices, length of stay, surgical and medical complications and early (30-day) or late (90-day) mortality rates. LVRS programs maintain these and other relevant data (e.g., number of procedures performed by individual practitioners). In sum, we expected that each LVRS program would take actions resulting in performance improvements and would track performance to ensure that improvements were sustained.

In order to provide adequate access to LVRS while preserving a high standard of care, CMS also concluded that the NETT results were likely to be applicable to lung transplant centers for which CMS had already developed criteria for approval under the Medicare program. We believed that the kind of integrated team assembled at the NETT sites with expertise in pulmonary medicine – especially as it related to end-stage emphysema, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, quality of life and dyspnea measurements, and pulmonary radiological assessment - would be present or could be established readily at Medicare-approved lung transplant facilities. We also understood that experienced lung and heart-lung transplant surgeons could perform LVRS with beneficial results, given the overlap of skills required for both surgical procedures.

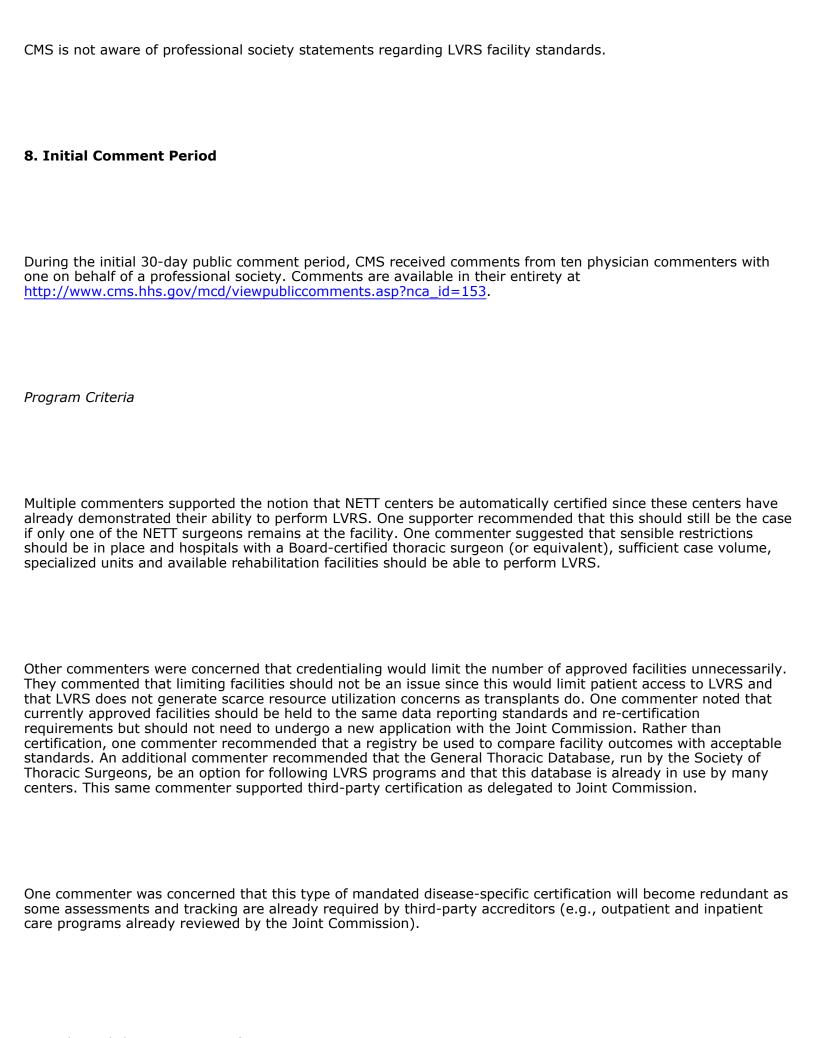
3. Joint Commission: Standard development

The proposal submitted to CMS for LVRS certification was developed within the framework common to all the disease-specific certification programs offered by the Joint Commission. It contains a core set of standards and the corresponding elements of performance for each standard applicable to the individual condition of interest, for example, stroke or asthma. Elements of performance are measurable characteristics used to evaluate compliance with standards and thus inform the Joint Commission's review procedures. Elements of performance specifically required for certification of LVRS facilities were incorporated into this framework.⁴

In order to develop the LVRS-specific elements of performance in its certification program, the Joint Commission assembled a task force composed of physicians representing the Society of Thoracic Surgeons, the American College of Chest Physicians, and other experts, including cardiothoracic surgeons. These selected experts provided their views on the characteristics critical to the structure and operation of a program capable of providing appropriate services centered on this procedure as well as on patient inclusion/exclusion criteria.

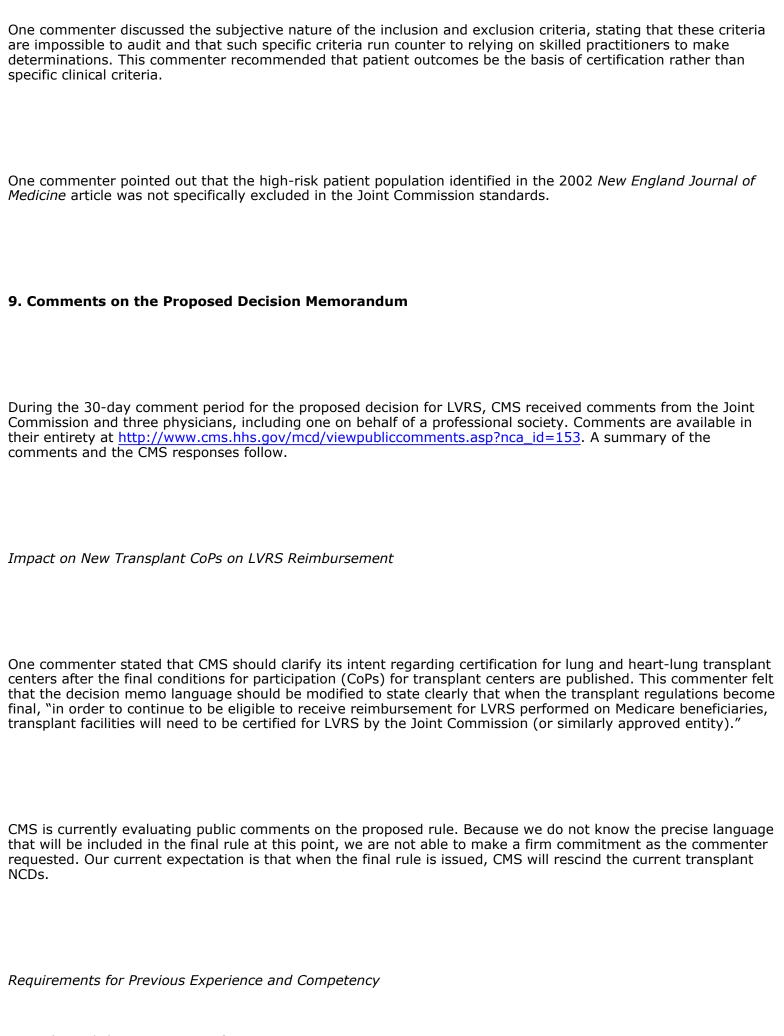
To obtain public input, the Joint Commission posted the proposed LVRS requirements on its web site and solicited comments directly from over 60,000 individuals enrolled on the Joint Commission ListServ. The comments received were incorporated where appropriate. The standards were reviewed again by the expert panel before a final LVRS certification program proposal was submitted to CMS.⁵

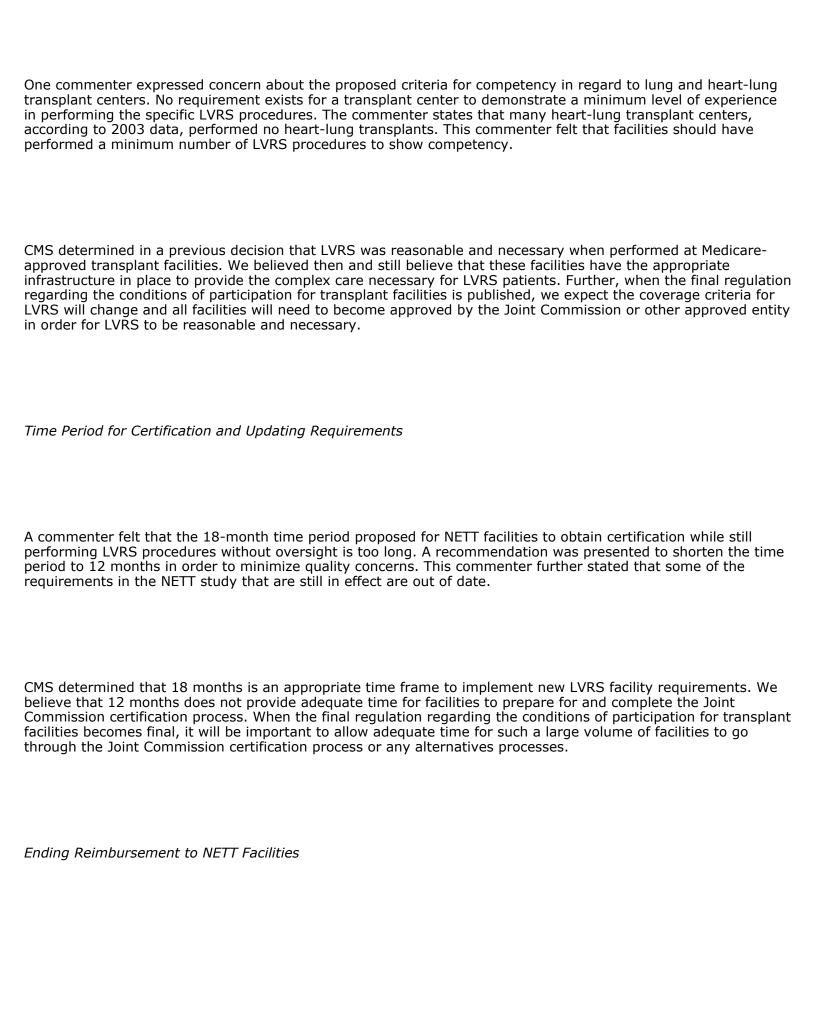
The LVRS certification program involves a two-year award cycle with an off-site and an on-site evaluation in the first year and an off-site intra-cycle evaluation during the second year. Certification is limited to hospital-based programs. Review of pre- and post-surgery rehabilitation services is to be conducted as part of the evaluation of the hospital program's ability to provide or coordinate all required services. The standards and elements of performance developed by the Joint Commission for LVRS certification are printed in the October 25, 2004, Disease-Specific Care Certification Program packet and are listed in Appendix A.
4. External technology assessments
No external technology assessment was commissioned for this review.
5. MCAC
The Medicare Coverage Advisory Committee was not convened to review this issue.
6. Evidence-based guidelines
CMS is not aware of professional guidelines for LVRS.
7. Professional Society Position Statements



Physician Criteria
Commenters stated that a Board-certified thoracic surgeon should be able to perform LVRS due to the lack of complexity of the procedure. One comment identified the Joint Commission's requirement for a minimum number of procedures as arbitrary. However, the same commenter did state that surgeons must be experienced and specialize in these types of cases and offered examples of other lung surgery experience that should deem a physician eligible to perform LVRS. Rather than physician competency, some commenters stated that patient selection and post-operative care management are primary drivers of patient outcomes. One commenter pointed out that the program certification criteria were inconsistent with the current Medicare requirements as the current criteria allow a transplant center with no LVRS experience to perform the procedure.
Coordination of Care
One commenter recommended that CMS eliminate the requirement that the surgical facility coordinate all preoperative services which include rehabilitation and post-operative services. The commenter stated that these requirements place unnecessary burden on the facility-based provider and sever the relationship between the patient and their local providers.
One commenter stated agreement with the Joint Commission and CMS requirement that patients should obtain evaluations for both LVRS and transplant and that non-transplant facilities should arrange for patients to be evaluated objectively and educated on the risks of LVRS versus transplantation.
Although some commenters supported data collection, one commenter specifically pointed out that this type of reporting should be done only when possible and that follow-up testing would be inconvenient and expensive for the patient.

Clinical Indications





One commenter, who presented his credentials as an early investigator in the field of thoracoscopic LVRS, a principal investigator in NETT, and extensive involvement in numerous publications on LVRS, was "dismayed by the proposed decision ending payment for LVRS for those programs that had participated in the NETT." This commenter felt this decision to be arbitrary and focused on the participation of his institution only, since he asserts that the other 16 of the 17 NETT centers are lung transplant centers. The commenter further stated that the decision would be counterproductive in a "quest for quality" since many transplant centers have little or no experience with LVRS, while his center has an established track record of excellence with LVRS. This commenter's qualifications and statements were supported by a second commenter who urged CMS to reconsider the plan to limit coverage of LVRS to centers that are approved lung transplant centers or approved by the Joint Commission. This second commenter felt that the vetting that was required to participate in the NETT, in combination with clinical experience, warrant continued inclusion as an approved LVRS center.

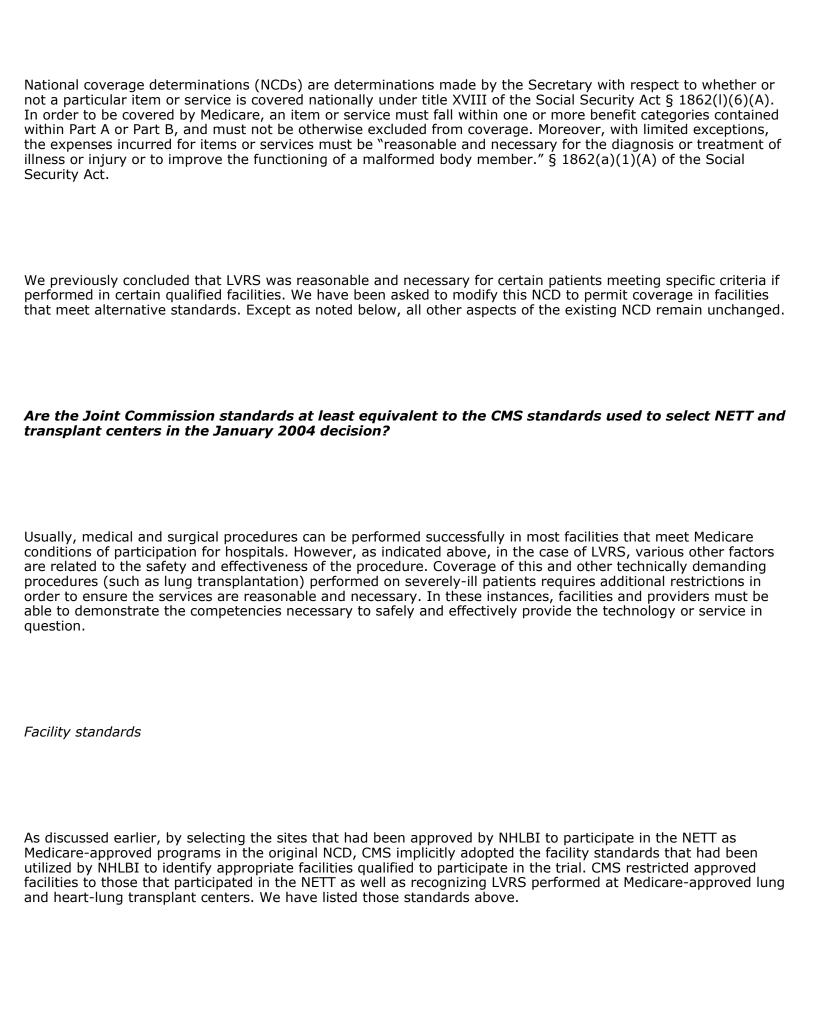
CMS understands the concerns raised by the commenters regarding NETT centers no longer automatically qualifying as Medicare approved for LVRS; however, we maintain the position expressed in this decision memorandum that since the formal relationship between the NETT centers and NHLBI no longer exists, CMS can not be assured that the NETT centers are maintaining the infrastructure by which they were once approved. For facilities such as the commenter's facility, we expect Joint Commission certification will be readily obtainable given the facility's experience, volume and professed outcomes.

Joint Commission Standards

A commenter, on behalf of the American Thoracic Society (ATS), agreed with the need to create a process in which additional facilities could demonstrate their competency in performing LVRS and qualify as a provider of this service for Medicare. However, the commenter expressed concern about the Joint Commission standards and how they depart from the NETT criteria. Specific concerns were identified in regard to an absence of patient selection criteria excluding patients from the high-risk group (patients with FEV1 < 20% and either diffuse disease or DLCO <20%); the lack of clear identification of a specific role of pulmonary rehabilitation prior to surgery: and the lack of a minimum 90-day post surgical mortality threshold to qualify as a LVRS provider. ATS encourages the inclusion of criteria for these three areas for qualifying LVRS providers.

The Joint Commission clinical inclusion and exclusion criteria does vary from the CMS policy, but the CMS policy on these clinical criteria will remain in effect for Medicare beneficiaries. Therefore, in order for claims to be paid by the Medicare program, Medicare beneficiaries who receive LVRS will still need to meet the clinical criteria outlined by CMS in the original LVRS NCD. This review was limited to facility criteria and did not change the clinical criteria. CMS has considered establishing a surgical mortality threshold. However, at this point, we do not feel comfortable establishing such an outcome threshold given that the only measures currently available are from the NETT clinical trial and they may not translate appropriately to routine practice.

VIII. CMS Analysis



The Joint Commission has established a disease-specific certification program for LVRS. The organization has requested through the NCD process that CMS approve its certification program. Although the Joint Commission standards include both patient selection and facility requirements, CMS is evaluating in this reconsideration those criteria related to facility standards only. Medicare payment for LVRS programs will continue to be limited to LVRS performed on beneficiaries who meet the patient clinical criteria outlined in our previous NCD.

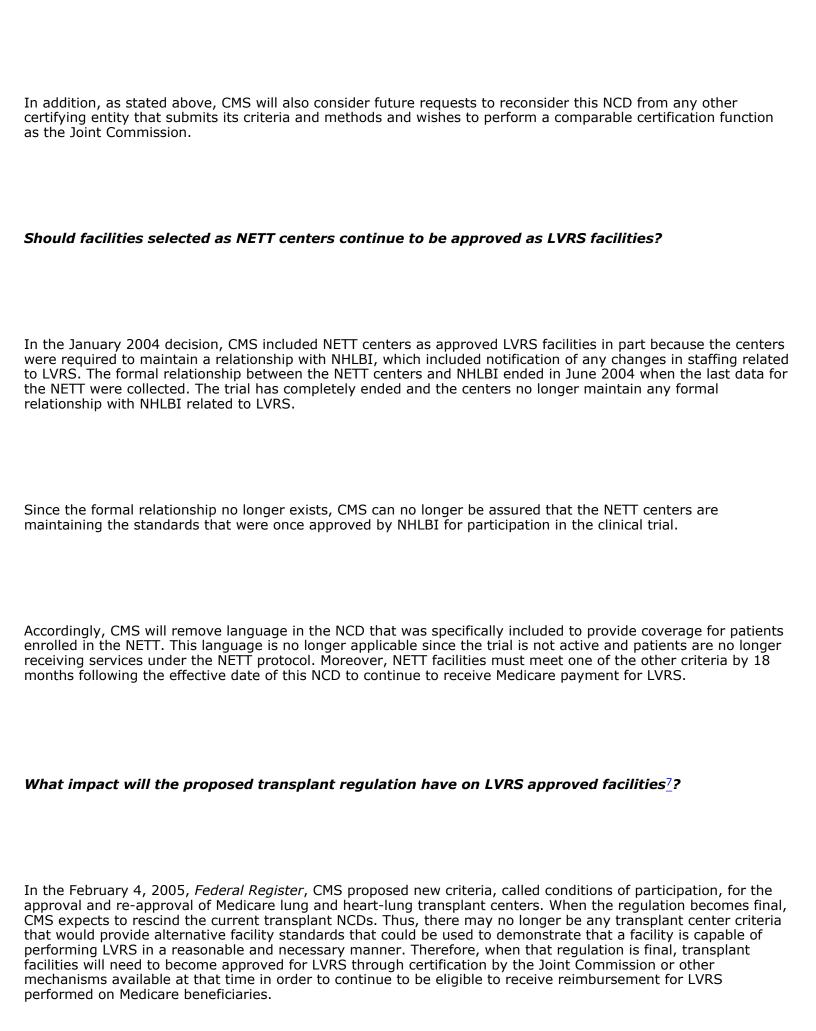
The facility requirements adopted by the Joint Commission appear to be derived directly from those originally developed by NHLBI to select facilities for the NETT trial. These are the facility requirements that CMS had implicitly adopted in its previous decision on LVRS. The Joint Commission certification program standards thus appear to be commensurate with the facility standards previously recognized by CMS as being adequate to ensure LVRS would be delivered in a reasonable and necessary manner. In addition, we note that the program has an organized approach to performance improvement, measures patient health outcomes, and allows participants to be actively involved in making decisions about their care.

In sum, the standards that the Joint Commission has established for certification of facilities furnishing LVRS services are consistent and equivalent with those CMS has found to be adequate to improve the health outcomes of Medicare beneficiaries. Adoption of the Joint Commission standards and methods will offer an opportunity for certification to any health care organization that shows the competence required to perform LVRS procedure successfully.

Not only do we believe that the Joint Commission standards are equivalent to the CMS standards, but we believe there are some significant additional benefits. The Joint Commission has incorporated specific performance measures and quality improvement requirements in its certification processes. The Joint Commission has also incorporated outcome measures. In addition, the certification program has a mechanism for facility re-approval and the Agency considers re-approval of LVRS facilities an unmet need.

For the reasons outlined above, CMS will include Joint Commission certification as an alternative mechanism for facilities to become approved to perform Medicare-covered LVRS. CMS reviewed the Joint Commission facility standards as printed in the October 25, 2004, Disease-Specific Care Certification Program packet and coverage of LVRS will include facilities approved under these particular standards beginning with the effective date of our NCD. Any changes in the facility standards in the Joint Commission certification program need to be reevaluated by CMS. Any facilities certified under altered standards, not approved by CMS, would not be eligible for payment for LVRS performed on Medicare beneficiaries.

The LVRS facility standards and the Joint Commission disease-specific certification process that we are incorporating into our national coverage determination are similar to but do not have the same legal effect as the standards and certification in 42 CFR Part 482 (Conditions of participation for hospitals). However, the options for certification as an LVRS facility identified in this NCD are considered necessary for LVRS to be reimbursed as reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act, but are not hospital conditions of participation.



IX. Conclusion Because the Joint Commission standards are at least equivalent to the current CMS LVRS facility standards, CMS has determined that LVRS is reasonable and necessary when performed at hospitals certified under the Joint Commission LVRS Disease-Specific Care Program as appropriate facilities to perform LVRS. CMS has determined that LVRS is reasonable and necessary at facilities that meet additional standards beyond those contained in our current NCD. Therefore, CMS is revising paragraph A.2.c in CMS Publication 100-3 Section 240.1 as follows: Effective for services performed on or after November 17, 2005, CMS determines that LVRS is reasonable and necessary when performed at facilities that are: (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or (2) approved as Medicare lung or heart-lung transplantation hospitals. In addition, LVRS performed between January 1, 2004 and May 17, 2007, is reasonable and necessary when performed at facilities that: (1) were approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT); or (2) are approved as Medicare lung or heart-lung transplantation hospitals. A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at

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